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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Amir Loshakove

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P.O. Box 16446

Arlington, VA 22215

EXAMINER

LUONG, PETER

ART UNIT

PAPER NUMBER

3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,383	Applicant(s) LOSHAKOVE ET AL.	
	Examiner Peter Luong	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,18,19,21,25,26,29-36,41,43,51,77 and 82-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,18,19,21,25,26,29-36,41,43,51,77 and 82-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 4/30/2008. These drawings are accepted.

Claim Objections

2. Claims 26 and 41 are objected to because of the following informalities: in claim 26, the limitation of "wherein said adhesive is sufficiently set as soon as said adhesive starts to set" is unclear and in claim 41 it is unclear whether as to how "a blood vessel" is related to the vessels previously set forth. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-4, 18-19, 29-31, 33-35, 43, and 82-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Popov et al. (US 6,068,637).
5. Regarding claim 1, Popov discloses a method of performing an anastomosis comprising juxtaposing two blood vessels to be anastomosed using a juxtaposition device (46, 48; 70, 72), to a desired configuration in which at least one vessel (10) is an end vessel, applying an adhesive to said vessels while they are in said configuration, said adhesive (70c and 72c) being sufficient to ensure both sealing and bonding of said two vessels to each other, and removing said juxtaposition device after said adhesive sufficiently sets, wherein the juxtaposition device remains primarily external to at least

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one of the vessels during the juxtaposing, (column 10 line 63 to column 11 line 14 and figures 10-11).

6. Regarding claims 3 and 4, Popov discloses a method according to claim 1 of inserting a part of his juxtaposition device (50) into the vessel and its wall (figure 6).

7. Regarding claim 18, Popov discloses a method according to claim 1, wherein applying comprises applying using a plurality of nozzles (70c and 72c) arranged in a ring, (column 10 line 63 to column 11 line 14 and figures 10-11).

8. Regarding claim 19, Popov discloses a method according to claim 1 wherein applying comprises applying into a mold adjacent said anastomosis area, which shapes the adhesive about said area, (column 10 line 63 to column 11 line 14 and figures 10-11).

9. Regarding claim 29, Popov discloses a method, which comprises removing all foreign materials other than the adhesive (column 11 lines 45-lines 57).

10. Regarding claim 30, Popov discloses a method of providing a strengthening element in an anastomosis site and leaving said strengthening element permanently in said anastomosis, (column 10 line 63 to column 11 line 14 and figures 10-11, examiner is interpreting “strengthening element” as a type of adhesive since when it cures it provides strength to the anastomosed area).

11. Regarding claims 31 and 33, Popov discloses a method of performing an anastomosis, comprising attaching at least a first external scaffold element (70) to a first blood vessel (10), wherein said first blood vessel is an end vessel (figures 10 and 11); attaching at least said first external scaffold element or a second external scaffold

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element (72) to a second blood vessel (12), figures 10-11); positioning said blood vessels using said at least a first scaffold element to a desired configuration (figure 10-11); applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other, and removing said at least first external scaffolding element (column 10 line 63 to column 11 line 14 and figures 10-11).

12. Regarding claims 34 and 35, Popov discloses a method according to claim 31, comprising mechanically attaching said at least first scaffolding element (14) to said first blood vessel; wherein mechanically attaching comprises piercing (30), (figure 2-4, column 9 line 50 to column 10 line 17, and column 10 line 63 to column 11 line 14, clips are being replaced with glue).

13. Regarding claim 43, Popov discloses a method according to claim 31, wherein said at least one scaffolding element comprises a balloon, (figure 19-20, column 15 line 33-44 and column 14 line 32-45).

14. Regarding claim 82, Popov discloses a method according to claim 1, wherein only one of said vessels (10) is an end vessel (figure 10-11, and column 10 line 63 to column 11 line 14 and figures 10-11).

15. Regarding claim 83, Popov discloses a method according to claim 1, wherein applying (the adhesive) is performed by the juxtaposition device, (figure 10-11 and column 10 line 63 to column 11 line 14).

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Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popov et al. (US 6,068,637) in view of Detweiler (US 5,141,516).

19. Popov discloses a method according to claim 1 wherein said (juxtaposition device) is removed once anastomosis is established. What Popov does not teach is removing said juxtaposition device before said adhesive "sets completely" and/or "starts to set." Detweiler discloses a method of performing an anastomosis, comprising; juxtaposing two blood vessels to be anastomosed using a juxtaposition device, to a desired configuration in which at least one vessel is an end vessel and removing said juxtaposition device after said adhesive sufficiently sets; wherein the juxtaposition

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device remains primarily internal to at least one of the vessels during the juxtaposing and is partially inserted into a wall of at least one of said vessels (column 6 line 51- column 7 line 24) and a method of removing juxtaposition devices before adhesive sets completely, wherein is stated the phrase "cured sufficiently" is not completely cured and the device is removed as soon as adhesive starts to set (column 7 lines 15-24). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Popov disclosure with the teaching in Detweiler to remove juxtaposition devices after adhesive is "cured sufficiently" in order to remove juxtaposition devices before the adhesive sets completely and as soon as adhesive starts to set.

20. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popov et al. (US 6,068,637) in view of Schenck et al. (US 4,553,542).

21. Popov discloses a method of performing an anastomosis, comprising attaching at least a first external scaffold element (70) to a first blood vessel (10), wherein said first blood vessel is an end vessel (figures 10 and 11); attaching at least said first external scaffold element or a second external scaffold element (72) to a second blood vessel (12), (figures 10-11); positioning said blood vessels using said at least a first scaffold element, to a desired configuration (figure 10- 11); applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other; and removing said at least first external scaffolding element (column 10 line 63 to column 11 line 14 and figures 10-11). Popov does not explicitly disclose a method wherein first blood vessel is a side vessel.

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Schenck discloses a method where a first external Scaffolding element is attached simultaneously to both side and end vessels, (figure 8, column 6 line 15-52). In light of the teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the external scaffolding in Popov, before applying the adhesive, with the teaching in Schenck to simultaneously attach external scaffolding to both side and end vessels.

22. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popov et al. (US 6,068,637) in view of Black et al. (US 6,245,083).

23. Popov discloses a method according to claim 31 wherein said at least one of said at least one scaffolding elements is removed once anastomosis is established. What Popov does not teach is, "removing said at least one of said at least one scaffolding elements before said adhesive sets." Black discloses a method similar to claim 31 except using internal scaffolding, wherein removing comprises removing at least one of said at least one scaffolding elements before said adhesive sets, (column 6 lines 51-57). In light of the obvious teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Popov disclosure with the teaching in Black to remove at least one of said at least one scaffolding elements before said adhesive sets.

24. Claims 1, 3-4, 31, 33-35, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff et al. (US 6,682,540) in view of Bessler (US 5,411,508).

25. Regarding claims 1 and 3-4, Sancoff discloses a method of performing an anastomosis, comprising; juxtaposing two blood vessels to be anastomosed using a

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juxtaposition device, to a desired configuration in which at least one vessel is an end vessel and removing said juxtaposition device after said adhesive sufficiently sets; wherein the juxtaposition device remains primarily external to at least one of the vessels during the juxtaposing and is partially inserted into a wall of at least one of said vessels. What Sancoff does not disclose is applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other. Alternatively, Sancoff applies sutures to said vessels while they are in said configuration. Bessler teaches that it is well known in the art to apply adhesive in place of sutures (Column 18 Lines 10-13). In light of the above of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Sancoff et al disclosure with the teaching in Bessler to apply adhesive at "said configuration" in place of sutures.

26. Regarding claims 31, 33-35, and 41, Sancoff discloses a method of performing an anastomosis, comprising; attaching at least a first external scaffold element (150) to a first blood vessel wherein first blood vessel is a end vessel (55); attaching at least said first external scaffold element or a second scaffold element (140) to a second blood vessel (65); positioning said blood vessels using said at least a first external scaffold element, to a desired configuration and removing said at least first scaffolding element (150), (Figures 21A-F and 22A-D). What Sancoff does not teach is applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other. Alternatively, Sancoff incorporates a scaffolding element (165), which comprises a

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plurality of wires (170) adapted to engage a blood vessel through piercing, in order to simultaneously place multiple sutures (Figures 21A-F and 22A-D). Bessler teaches that it is well known in the art to apply adhesive in place of suturing (Column 18 Lines 10-13). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Sancoff et al disclosure with the teaching in Bessler et al to apply adhesive to the tissue ends in place of sutures after the plurality of wires have engaged the vessels through piercing.

27. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff et al. (US 6,682,540) in view of Bessler (US 5,411,508) as applied to claim 1, further in view of Redl et al. (US 4,631,055).

28. Sancoff discloses the subject matter substantially as claimed except for "applying (adhesive) using a plurality of nozzles arranged in a ring." Bessler teaches applying (adhesive) using a plurality of nozzles arranged in a ring but does not disclose a juxtaposition device external to the blood vessels (column 17 lines 62-65 and column 18 lines 53-57, figure 10A-C). Redl discloses a device comprising a plurality of nozzles to apply adhesive, (column 1 lines 12-18 and column 3 line 50 to column 4 line 10, Figures 1-4, cone is equivalent to a nozzle). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Sancoff et al disclosure with the teachings in Bessler and Redl to apply (adhesive) using a plurality of nozzles arranged in a ring.

29. Claims 21 and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff et al. (US 6,682,540) in view of Bessler (US 5,411,508) as applied to claims 1

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and 34, further in view of Buijsrogge et al, "Sutureless coronary anastomosis with an anastomotic device and tissue adhesive in off-pump porcine coronary bypass grafting".

30. Regarding claim 21, Sancoff discloses the subject matter substantially as claimed except for a measured amount of adhesive. Buijsrogge teaches a method comprising applying a pre-measured amount of adhesive (pg 790(2), Anastomotic Procedure, lines 13 to 25). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Sancoff et al disclosure with the teachings in Bessler and Buijsrogge to apply a pre-measured amount of adhesive to an anastomosis site.

31. Regarding claim 36, Sancoff discloses the subject matter substantially as claimed. Sancoff teaches scaffolding that is mechanically attached via hooking, he does not teach using an adhesive to seal and bond vessels. Buijsrogge teaches using an adhesive to seal and bond vessels after incorporating a scaffolding element that is mechanically attached to blood vessel engagement region through hooking. In light of the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Sancoff et al disclosure with the teaching in Bessler et al to apply adhesive to the tissue ends in place of sutures and to engage the vessels using a scaffolding with hooks before applying adhesive.

32. Claims 77 and 84-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholas et al. (US 20010029384) in view of Popov (US 6,068,637).

33. Nicholas discloses a first blood vessel holder (116a); a second blood vessel holder (116b) adapted to interlock with said first blood vessel holder such that blood

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vessels held by said two vessel holders contact (figures 2-8). Nicholas also discloses a method wherein only one of said vessels is an end vessel and wherein the first blood vessel holder and the second blood vessel holder are each substantially outside their respective blood vessels (figures 14-17). However Nicholas does not teach an adhesive port on at least one of said first vessel holder and said second vessel holder, said port configured to deliver an adhesive to said contact at an external portion of the contact. Instead, Nicholas discloses a port on at least first vessel holder configured to deliver clips to said contact at an external portion of the contact (paragraph 85 line 1 to paragraph 87 line 11). Popov teaches a first blood vessel holder and a second blood vessel holder as well as an adhesive port on both vessel holders configured to deliver an adhesive to said contact at an external portion of the contact. Popov additionally discloses a method wherein only one of said vessels is an end vessel, wherein the first blood vessel holder and second blood vessel holder are each substantially outside their respective blood vessels (figures 10-11 and column 10 line 63 to column 11 line 14). Alternatively, Popov teaches a method wherein the adhesive ports (figures 10-11) on the vessel holders are replaced by clip delivery ports (figures 8-9) (column 10 lines 31-67). However Popov does not teach a means for the two vessel holders to interlock such that the two blood vessels contact. In light of the above teachings there is motivation for a person of ordinary skill in the art at the time the invention was made to have modified the Nicholas disclosure with the teaching in Popov to deliver an adhesive to the contact point between vessels in place of clips. With respect to claim 86, it would have been obvious to one of ordinary skill in the art at the time the invention was made

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to have removed the device after the procedure as one of ordinary skill in the art would know not to leave a foreign object inside the patient's body.

Response to Arguments

Applicant's arguments filed 4/30/2008 have been fully considered but they are not persuasive.

Applicant argues Popov et al. does not teach wherein the first vessel is an end vessel. However, the Examiner respectfully disagrees with the Applicant. Popov et al. discloses "performing end-to-side anastomoses between the severed end of a first hollow organ and the side-wall of a second hollow organ", abstract line 1.

Applicant argues Popov et al. does not teach a juxtaposition device or scaffolding elements. However, the Examiner respectfully disagrees with the Applicant. Popov et al. teaches clips 46 and 48 to secure the blood vessels in sealing engagement. Furthermore, the Examiner notes that the general definition of juxtapose is to place close together or side by side and the general definition of scaffold is to provide support. Therefore, the glue appliers (70, 72) are both juxtaposition devices and scaffolding elements as the appliers provide support for the blood vessels during the application of the adhesive and, in doing so, places the vessels close together.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

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the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Popov et al. teaches the method steps substantially as claimed except for whether the adhesive is sufficiently set. The secondary references, in the same field of endeavor, taught when the adhesive was sufficiently set.

Applicant argues that Sancoff does not teach removing the device after the adhesive sets and the device remains primarily external to the vessel. However, the Examiner respectfully disagrees with the Applicant. As stated by the Applicant, response page 13 paragraph 3, "section 150 is placed over the first blood vessel", therefore it is external to the vessel, and "afterwards, the sections 140 and 150 may be removed", therefore the device is removable.

Applicant argues that Nicholas does not teach a first and second vessel holder. However, the Examiner disagrees with the Applicant. Applicant's claim recites a first blood vessel holder and a second blood vessel holder adapted to interlock with said first blood vessel holder. As interpreted by the Examiner, Nicholas teaches a first and second holder adapted to interlock. Applicant's claim does not require the holders to hold separate vessels.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571)270-1609. The examiner can normally be reached on Monday - Friday, 9:30 a.m. - 6:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

/Peter Luong/
Examiner, Art Unit 3737